INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/014935 CLASSIFICATION OF SUBJECT MATTER Int.Cl⁷ C07K16/00, A61K9/08, 39/395, 47/02, 47/18, 47/26, A61P35/00 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) C07K16/00, A61K9/08, 39/395, 47/02, 47/18, 47/26, A61P35/00 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) MEDLINE(SNT), BIOSIS(STN), WPIDS(STN), JICST FILE(JOIS) C. DOCUMENTS CONSIDERED TO BE RELEVANT Category* Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. Х JP 2001-504092 A (Rotkreuzstifung 1 - 4, 9Α Zentrallaboratorium Blutspendedienst SRK), 10,11 27 March, 2001 (27.03.01), Claims; examples & EP 835880 A1 & WO 98/16558 A1 & US 6136312 A1 Х JP 9-127114 A (Dainabot Co., Ltd.), 1-3,9,10 Α 16 May, 1997 (16.05.97), 4,11 Claims; example 1; Fig. 1 (Family: none) Х JP 9-127112 A (Dainabot Co., Ltd.), 1-3,9-11 Α 16 May, 1997 (16.05.97), 4 Claims; example 1; Fig. 1 (Family: none) Further documents are listed in the continuation of Box C. See patent family annex. Special categories of cited documents: later document published after the international filing date or priority date and not in conflict with the application but cited to understand "A" document defining the general state of the art which is not considered to be of particular relevance the principle or theory underlying the invention "E" earlier application or patent but published on or after the international document of particular relevance; the claimed invention cannot be filing date considered novel or cannot be considered to involve an inventive step when the document is taken alone document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other document of particular relevance; the claimed invention cannot be special reason (as specified) considered to involve an inventive step when the document is combined with one or more other such documents, such combination document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but later than the being obvious to a person skilled in the art "&" document member of the same patent family priority date claimed Date of the actual completion of the international search Date of mailing of the international search report 04 January, 2005 (04.01.05) 25 January, 2005 (25.01.05)

Authorized officer

Telephone No.

Form PCT/ISA/210 (second sheet) (January 2004)

Japanese Patent Office

Name and mailing address of the ISA/

Facsimile No.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2004/014935

	· · · · ·	PC1/0P20	04/014935
C (Continuation)	DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relev	ant passages	Relevant to claim No.
X A	JP 2-786335 A (Biotest Wolfram), 19 March, 1990 (19.03.90), Claims; page 3, upper left column; examples & EP 352500 A & US 5190752 A		1-4,9 10,11
X A	JP 2-493 A (Miles Inc.), 05 January, 1990 (05.01.90), Claims; examples; page 5, upper right col & EP 303088 A & US 5157113 A	lumn	1-4,9,10
х	GOMBOTZ WR et al., "The stabilization of human IgM monoclonal antibody with poly (vinylpyrrolidone)." Pharm Res., 1994, Vol.11, No.5, page 624-32	a	1-4,9-11
A	DRABER P. et al., "Stability of monoclone IgM antibodies freeze-dried in the present of trehalose." J Immunol Methods., 1995, Vol.181, No.1, pages 37 to 43	al nce	1-4,9-11
		*	
		:	
			-

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP2004/014935

	INTERNATIONAL SELECTION	
	Observations where certain claims were found un	hable (Continuation of item 2 of first sheet)
	have certain claims were found un	searchable (CC
oz No. II	Observations where co.	ertain claims under Article 17(2)(a) for the following reasons:
	Lished in respect of c	ertain claims under Article 17(27(27)
	onal search report has not been established in the	
his internati	onal search report has here or its loss of the sear ims Nos.: Lause they relate to subject matter not required to be sear.	ched by this Authority, namely:
. L Cla	ims Nos.:	Since of
bec	ause they relate to subject	
		that do not comply with the prescribed requirements to such an ied out, specifically:
_		that do not comply with the prescribed requirement
2. 🔲 C	laims Nos.: ecause they relate to parts of the international application xtent that no meaningful international search can be carr	ied out, specifically:
ь	ecause they relate to partial ecause they relate to partial international search can be can	
e	xtent that no meaning	
ı		
ı		satisficentences of Rule 6.4(a).
l	e a series de la companya de la comp	accordance with the second and third sentences
3.	Claims Nos.:	n accordance with the second and third sentences of Rule 6.4(a).
1	because they are department	of item 3 of first sheet)
L	less unity of invention is lac	king (Continuation of the
Box No.	Descriptions where unity of invention is lacternational Searching Authority found multiple invention as matter common to claims 1 to 3.	as in this international application, as follows: 5 is the stabilization of an IgM solution 6 coument (JP 2001-504092 A (Rotkreuzstifung 7 March, 2001 (27.03.01))
BUA 110		
This Int	ernational Searching Administration Claims 1 to 3.	5 is the stabilization of a high concentration, and thus, it on of a high concentration said document
T	ne matter common and a high concentration. a high concentration that the do	ocument (JP 2001-504032
of	a high concern and has revealed that the de	enst SRK) 27 March, 2001 (27.03.017) enst SRK) 27 March, 2001 (27.03.017) on of a high concentration, and thus, it on of a high concentration said document nmon matter is disclosed in said document sult, the stabilization of an IgM solution sult, the stabilization art, and therefore,
T!	he search has Blutspendedic	on of a high concentration in said document
Zen	trallabolated lgM solution	mon matter is disclosed of an IgM solution
des	scribes a scapthat the above con	sult, the stabilization of and therefore,
has	become creat not novel. As a re	enst SRK) 2/ Match, and thus, report of a high concentration, and thus, report of a high concentration, and thus, report of a high concentration of an IgM solution sult, the stabilization of an IgM solution sult, the stabilization art, and therefore, and the scope of the prior art, and therefore, and the scope of the prior art, and therefore, and the scope of the prior art, and therefore, and the scope of the prior art, and therefore, and the scope of the prior art, and therefore, and the scope of the prior art, and therefore, and the scope of the prior art, and thus, remains the scope of the prior art, and the scope of the prior art are the scope of the prior ar
and	- contration Idlia Wil	atal technical room axtra sheet/
of	a high commatter cannot be a spec	nmon matter is disation of an IgM solution sult, the stabilization of an IgM solution sult, the stabilization of an IgM solution stability in the scope of the prior art, and therefore, the scope of the prior art, and therefore, the scope of the stability is also at the scope of
th	d therefore is not novel. As a load therefore is not	the applicant, this international search report covers
in		
1.[As all required additional scales.	ffort justifying an additional fee, this Authority did not invite payment of
- 1	-laims	on A suctificity all addition
2. [As all searchable claims could be searched with	s were timely paid by the applicant, this international search report covers fically claims Nos.:
12.1	00011101121 1002	and time Piv Dalu VI
\ \	of the required additional search rec	Scally claims Nos.:
3.	As only some of the required additional search feet only those claims for which fees were paid, speci	nearly 4
1	only those claims is	•
1		
1		
1.		aturable international search report is
1		coid by the applicant. Consequently, this internal
\	additional search fees were timely	paid of the covered by claims Nos.:
\ 4	No required additional search fees were timely restricted to the invention first mentioned in the	paid by the applicant. Consequently, this international search report is claims; it is covered by claims Nos.:
\	restricted to and	•
1	a o to 11	
1	Claims 1 co	ch fees were accompanied by the applicant's protest.
1	The additional sear	ch fees were accompany to a search fees.
1	Remark on Protest The additional see	anied the payment of additional search fees.
1	No protest accomp	M****
1		
1	to the second se	
		2004)

COPY SUBMITTED IN IDS

INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP2004/014935

Continuation of Box No.III of continuation of first sheet(2)

are classified into a group of inventions according to claims 1 to 4 and 9 to 11 relating to a solution containing a stabilized immunoglobulin at a high concentration, wherein the immunoglobulin is IgM, a group of inventions according to claims 5 to 8, 13 to 22, 24 to 34 having a technical feature of a high concentration IgM solution containing a multi-valent cationic ion, and a group of inventions according to claims 12, 23 and 35 having a technical feature of the freezing or freeze-drying of a stabilized IgM solution of a high concentration.

Form PCT/ISA/210 (extra sheet) (January 2004)